AUG - 8 2003

C Summary

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: K030579 (applicant leave blank)

Premarket Notification [510(k)] Summary

[(a)(1)]. The summary contains on the first page, preferably on your letterhead paper, the submitter's name, address, phone and fax numbers, name of contact person, and date the summary was prepared :

Submitter's name :	JDA (TIANJIN) PLASTIC RUBBER CO., LTD.
Submitter's address :	17 HAIBIN 7 RD. TIANJIN TREE TRADE ZONE, TIANJIN ,300456,P.R.China
Phone number :	(86)22-25760468
Fax number :	(86)22-25760466
Name of contact person:	Wan Dong Hua,-Technology Department Manager
Date the summary was prepared:	23 May 2003

[(a)(2)]. The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known

Device Name	Nitrile powder-free patient examination glove
Proprietary/Trade name:	LEGEND™ Nitrile powder-free patient examination glove
Common Name:	Other clients private labeling Patient examination glove
Classification Name:	Patient examination glove
Device Classification:	I
Regulation Number:	21 CFR 880.6250
Panel:	General Hospital (80)
Product Code:	LZA

[(a)(3)]. An identification of the legally marketed device to which your firm is claiming substantial equivalence .

Class I* Nitrile powder-free patient examination, that meets all of the requirements of ASTM standard D 6319-00ae3.

Predicate device : Nitrile powder-free patient examination glove, JDA International Inc. k993247 .

[(a)(4)] A description of the device

K030529

Device Description : Nitrile powder-free patient examination, that meets all of the requirements of ASTM standard D 6319-00ae3.

[(a)(5)] The summary describes the intended use of the device

Device Intended Use: Nitrile powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

[(a)(6)] A summary of the technological characteristics of new device compared to the predicate device.

The nitrile powder-free patient examination glove, non sterile are summarized with the following technological characteristics compared to ASTM or equivalent standard.

Characteristics	Standard	Device performance
Dimension	ASTM standard D 6319-00ae3.	Meets
Physical Properties	ASTM standard D 6319-00ae3.	Meets
Freedom from pinholes	21 CFR 800.20	Meets
Powder Residual	ASTM standard D 6124-01	Meets <2mg/glove
Biocompatability	Primary Skin Irritation in rabbits	Passes Not a Primary Skin Irritation
	Dermal sensitization in the guinea pig	Passes Not a Dermal sensitization

[(b)(1)] A brief discussion of the nonclinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence .

Nitrile powder-free patient examination glove meet requirements per ASTM D6319-00ae3, per ASTM D6124-01, per 21 CFR 800.20 and ISO10993-10.

[(b)(2)] A brief discussion of the clinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence .

Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

[(b)(3)] The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe,as effective, and performed as well or better than the legally marketed device identified in (a)(3).

It can be concluded that the LEGEND™ Nitrile powder-free patient examination gloves meet the ASTM standard or equivalent standard and FDA requirements for waterleak test on pinhole AQL., meet labeling claims .

K030529

Appendix 2.0 Product specification

The Nitrile powder-free patient examination glove meet **ALL** the current specifications listed under the ASTM Specification D 6319-00ae3.

1. Dimension

(mm)

DEMENTION	ASTM D6319-00ae3	LEGEND'S
Palm Width		
Small	80+/-10	80-90
Medium	95 +/-10	90-100
Large	110 +/-10	100-110
X-Large	120 +/-10	110-120
Length		
Small	220 min	240-250
Medium	230 min	for all sizes
Large	230 min	
X-Large	230 min	
Thickness		
finger	0.05 min	0.12+/-0.01
palm	0.05 min	0.12+/-0.01

2. Physical properties

(mm)

	Tensile strength (MPa)		Ultimate elongation(%)	
	ASTM D6319-00ae3	LEGEND'S	ASTM D6319-00ae3	LEGEND'S
Before aging Small Medium Large x-large	14 min	19.0 min	500 min	630min
After aging 22hours@100℃ Small Medium Large x-large	14 min	19.0min	400 min	530min

3. Water Tight Test

The pinhole or leak testing, the sampling and testing conform to the test methods and AQL established by the manufacturer under their quality system acceptance criteria in 21 CFR 820.181.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2003

JDA Tianjin Plastic Rubber Company, Limited
C/O Mr. Chen Yuhong
TUV Rheinland Beijing Office
Rm 707 Avic Bldg. 2 Dong San
Huan Nan Road Chaoyang District
BEIJING 100022, P.R. CHINA

Re: K030529
Trade/Device Name: Legend (Brand) Nitrile Powder-Free Patient Examination Glove
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: April 23, 2003
Received: June 2, 2003

Dear Mr. Yuhong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K030529

3.0 Indications for Use Statement: Include the following or equivalent Indications for Use page. The information, data and labeling claims in the entire 510(k) submission must support and agree with the Indications for Use statement.

INDICATIONS FOR USE

Applicant: JDA (Tianjin) Plastic Rubber Co., Ltd.

510(k) Number (if known): *

Device Name: Nitrile powder-free patient examination glove, Blue Color

Indications For Use:

Nitrile powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Clin S. Lin

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030529